

Message Text

UNCLASSIFIED

PAGE 01 STATE 003161
ORIGIN HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-06 EB-07 COME-00 /032 R

DRAFTED BY:EHEW/FDA:LRSHELTON, DIRECTOR
APPROVED BY:OES/APT/BMP: WJWALSH, III
DHEW/OIH:BROYSTER
EUR/WE:JFDOBBINS(INF)
EUR/NE:CWSCHALLER(INFO)
EUR/NE:DJDOHCHI(INFO)
EUR/CE:KAKURZE(INFO)
EUR/NE:KHSHIRLEY(INFO)

-----070727Z 100341 /15

R 070008Z JAN 77
FM SECSTATE WASHDC
TO AMEMBASSY COPENHAGEN
AMEMBASSY OSLO
AMEMBASSY BONN
AMEMBASSY THE HAGUE
AMEMBASSY PARIS

UNCLAS STATE 003161

E.O. 11652: N/A

TAGS: OGEN, OTRA, TBIO, DA, NO, NL, FR

SUBJECT: FDA REPRESENTATIVES PROVIDING CONSULTATION TO
DRUG MANUFACTURERS

1. FDA ADVISES THAT TWO INVESTIGATORS - FRANK BARNES AND
GERALD SCHOLZE - WILL BE IN EUROPE FEBRUARY 12-MARCH 14,
1977 TO INSPECT FIVE ANTIBIOTIC-PRODUCERS AND TWO DRUG MAN-
UFACTURING CONCERNS.

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2. THESE VISITS WILL BE MADE TO DETERMINE IF THE FIRMS'
FACILITIES AND OPERATIONS ARE IN ACCORDANCE WITH CURRENT
GOOD MANUFACTURING PRACTICE REGULATIONS, AND TO REPORT ANY
SIGNIFICANT DEVIATIONS IN THEIR PROCESSES OR CONTROLS WHICH
WOULD HAVE AN ADVERSE EFFECT UPON THE SAFETY OR EFFICACY OF
THE PRODUCTS BEING SHIPPED TO THE U.S.

3. ITINERARY:

FEBRUARY 12: ARRIVE COPENHAGEN
FEBRUARY 14-15: INSPECT NOVO
FEBRUARY 17-18: INSPECT DUMEX
FEBRUARY 21-22: INSPECT LUNDBECK
FEBRUARY 23: TRAVEL TO OSLO
FEBRUARY 24-25: INSPECT APOTHEKERNES
FEBRUARY 28: TRAVEL TO BAD HOENNIGEN
MARCH 1: INSPECT KALI-C;EMIE
MARCH 3: TRAVEL TO DELFT
MARCH 4, 7: INSPECT GIST
MARCH 9: TRAVEL TO DAX
MARCH 10-11: INSPECT RESINIKUES
MARCH 14: DEPART FOR U.S.

4. ASSISTANCE OF POSTS WILL NOT BE REQUIRED.
KISSINGER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: DRUG INDUSTRY, ITINERARY, DRUG PREPARATION, CONSULTANTS, INSPECTIONS, VISITS, INVESTIGATIONS, FOOD & DRUG REGULATIONS
Control Number: n/a
Copy: SINGLE
Sent Date: 07-Jan-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE003161
Document Source: CORE
Document Unique ID: 00
Drafter: EHEW/FDA:LRSHELTON, DIRECTOR
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770018-0494, D770006-0854
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t19770171/aaaacjxk.tel
Line Count: 81
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 2b8e30dc-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 22-Oct-2004 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 3643598
Secure: OPEN
Status: NATIVE
Subject: FDA REPRESENTATIVES PROVIDING CONSULTATION TO DRUG MANUFACTURERS
TAGS: OGEN, OTRA, TBIO, DA, NO, NL, FR, FDA, (BARNES, FRANK), (SCHOLZE, GERALD)
To: COPENHAGEN OSLO MULTIPLE
Type: TE
vdkgvkey: odbc://SAS/SAS.dbo.SAS_Docs/2b8e30dc-c288-dd11-92da-001cc4696bcc
Review Markings:
Margaret P. Grafeld
Declassified/Released
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